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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,965	04/13/2004	Patrick James Lennon	PC27705A	5459
28523	7590	12/15/2004	EXAMINER	
PFIZER INC.			NWAONICHA, CHUKWUMA O	
PATENT DEPARTMENT, MS8260-1611			ART UNIT	PAPER NUMBER
EASTERN POINT ROAD				
GROTON, CT 06340			1621	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/823,965	LENNON ET AL.
	Examiner	Art Unit
	Chukwuma O. Nwaonicha	1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
 - 4a) Of the above claim(s) 25-34 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

DETAILED ACTION

Claims 1-34 are pending in the application.

Priority

Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, drawn to a quarternary ammonium compound, classified in class 564, subclass 282.
- II. Claim 25-34, drawn to a method of treating pulmonary diseases, classified in class 514, subclass 223.8.

Inventions of Group I and Group II are related as product and method of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process for using the product as claimed can be practiced with another materially different product or (2) that the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product, such as quarternary ammonium compound (WO 03/035599) and WO 02/096855.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, a search of the two groups designated above would

impose an undue burden upon the examiner, and restriction for examination purposes as indicated is proper.

During a telephone conversation with Robert Ronau on 12/2/04, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 25-34 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicants' are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

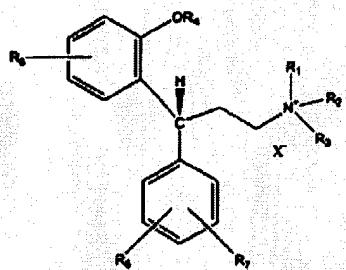
Claims 1-4, 8-22 and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8-22 and 25 of copending Application No. 10280906 in view of Lennon et al. This is a provisional obviousness-type double patenting rejection.

The presently claimed quarternary ammonium compounds and their compositions are disclosed in copending Application No. 10280906. See the entire specification of the copending Application No. 10280906.

Applicants claim a quarternary ammonium compounds of the general formula I or a stereoisomer thereof:

We Claim:

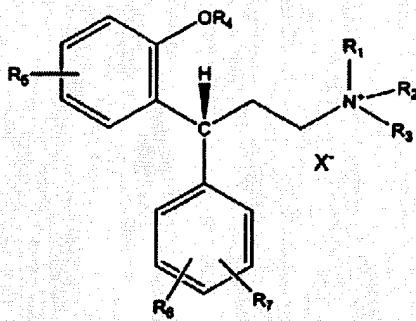
1. A quaternary ammonium compound of the formula



formula I

wherein all the variables are as defined in the claims while Application No. 10280906 teaches quaternary ammonium compounds of the general formula shown below:

Claim 1 (Original): A quaternary ammonium compound of the formula



and any stereoisomers thereof, wherein

R1, R2 and R3 independently represent C1-C6 alkyl, optionally substituted with phenyl or hydroxyl, or both, and wherein any two of R1, R2 and R3 may form a ring together with the quaternary ammonium nitrogen;

R4 represents

-H,

-CH3, or

-CO-R4a, wherein R4a represents

-(C1-C4 alkyl),

-(C1-C4 alkoxy), or

-NR4a2R4a3, wherein R4a2 and R4a3

independently represent -H or -(C1-C4 alkyl);

R5, R6 and R7 independently represent

-H,

-OCH3,

-OH,

-CONH2,

-SO2NH2,

-F, -Cl, -Br, -I,

-CF3, or

-(C1-C4 alkyl), optionally substituted with one or two

-OH,

-(C1-C4 alkoxy),

-COOH, or

-CO-O-(C1-C4 alkyl); and

X- represents an anion of a pharmaceutically acceptable acid.

See pages 2-6 of the claim.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims overlaps substantially with the scope of claims 1-4, 8-22 and 25 in the copending Application No. 10280906, and the genus of presently claimed invention encompasses the species in copending Application No.

10280906. They differ in that Application No. 10280906 compounds are a subgenus of the claimed compounds. This difference is not a patentable distinction because in Application No. 10280906 teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill in the art.

Therefore, the instantly claimed compounds would have been suggested to one of ordinary skill because one of ordinary skill in the art would have a reasonable expectation of success in practicing the instant invention since Application No. 10280906 specifically discloses the quarternary ammonium compounds. Said person would have been motivated to practice the teachings of the copending Application No. 10280906 by varying the substituents to arrive at the instant invention since the reference demonstrates that quarternary ammonium compounds are useful in treating pulmonary disease such as asthma. The instantly claimed compounds would therefore have been suggested to one of ordinary skill in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

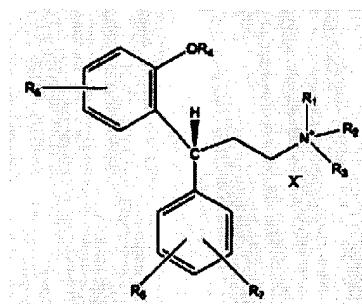
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the

United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Richards et al., {WO 03/035599}.

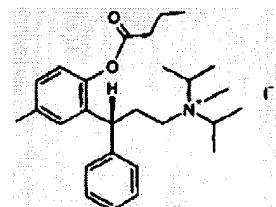
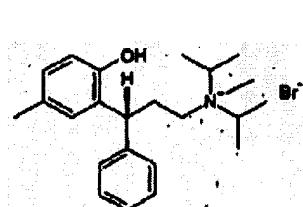
Applicants claim a quarternary ammonium compound and its composition of general formula I, and method of use:



I

wherein all the variables are as defined in the claims.

Richards et al. disclose quarternary ammonium compounds and their compositions as claimed by applicants.



See pages 23-43.

No claim is allowed.

Any inquiry concerning this comm. unication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is

571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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